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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,008	07/14/2003	Patricia J. Andolino Brandt	53867US018	6035

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EXAMINER

GEORGE, KONATA M

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/619,008	<b>Applicant(s)</b> ANDOLINO BRANDT ET AL.	
	<b>Examiner</b> Konata M. George	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 is/are allowed.
- 6) ☒ Claim(s) 1,2,6,10,12 and 17 is/are rejected.
- 7) ☒ Claim(s) 3-5,7,9,11,18 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-7, 9-12 and 14-19 are pending in this application.

#### ***Action Summary***

1. Examiner acknowledges the cancellation of claims 8 and 13. Therefore, any and all rejections directed towards them is hereby withdrawn.
2. Applicant's election without traverse of Group I, claims 1-13, 15 and 17-19 in the reply filed on August 13, 2004 is acknowledged.
3. The rejection of claims 1 and 6-8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,627,216 is hereby withdrawn as applicant has filed a terminal disclaimer.
4. The rejection of claims 1-7, 9-12, 15 and 17-19 over 35 U.S.C. 112 second paragraph is hereby withdrawn as applicant has defined the "surface" as being skin, oral tissue and wounds.
5. The rejection of claim 10 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn as applicant has remove the indefinite terminology from the claim.
6. The rejection of claims 1-4, 6, 7, 9-12, 15, 17 and 18 under 35 U.S.C. 103(a) over Salamone et al. is hereby withdrawn.

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***Response to Arguments***

7. Applicant's arguments with respect to claims 1, 2, 6, 9, 10, 12 and 17 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-7, 9-12, 14 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant in the claims recite the phrase "effective amount", however, have not defined in the claims how much is considered an "effective amount". Please define how much is considered an effective amount with respect to the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 6, 10, 12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by (WO 88/09185 translated into European Patent Specification 0 319 555 B1).

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Burghart discloses in example 3, page 6 a liquid composition that forms a film when applied to the skin. The composition comprises a butyl ester of polymethacrylic acid (equivalent to the tacky component describe in claims 1(a), 2 and 17 (a)), vinylpyrrolidone-vinylacetate copolymer (equivalent to the non-tacky component describe in claims 1(b), 6 and 17(b)) and an ethanol (equivalent to the volatile solvent describe in claims 1(c), 10 and 17(c)). The composition also contains a therapeutically effective amount of a pharmacologically active agent (10% ethanol nitroglycerin solution). Although it is not specifically disclosed by the prior art that the film-forming, non-tacky component comprises at least one low surface energy, surface seeking moiety and upon application undergoes phase separation from the tacky component, it is the position of the examiner that since the component as claimed by applicant and disclosed by the prior art are equivalent with respect to claim 2, then it would also contain the same functionalities.

***Allowable Subject Matter***

10. Claims 3-5, 7, 9, 11, 8 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose that the tacky component is a copolymer of monomers comprising about 40 to 100 weight percent of an alkyl (meth)acrylate and 0 to about 60 weight percent of a free radically copolymerizable monomer. It is also not taught the non-tacky component

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comprising a siloxane containing polymer and that the weight ratio between the tacky and non-tacky components are in the range of 1:10 to about 10:1.

11. Claim 15 is allowed. The prior art does not teach the composition as claimed.

### ***Conclusion***

12. Claims 1-7, 9-12, 14 and 17-19 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

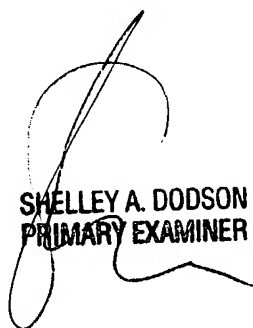
***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

  
**SHELLEY A. DODSON**  
**PRIMARY EXAMINER**